



AdvaMed

Advanced Medical Technology Association

FREQUENTLY ASKED QUESTIONS

REGARDING ADVAMED'S CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

SECTION I: PREAMBLE AND GENERAL QUESTIONS

Q1 Why did AdvaMed develop a code distinct from the PhRMA Code on Interactions with Health Care Professionals?

The AdvaMed Code of Ethics is intended to address the unique interactions that occur between Companies and Health Care Professionals, just as the PhRMA Code reflects the nature of interactions between pharmaceutical companies and Health Care Professionals. Distinguishing features in AdvaMed's Code arise primarily from the fact that Companies interact with Health Care Professionals because of the complexity and "hands on" nature of Medical Technologies and the importance of having Health Care Professionals understand how to use the technologies safely and effectively.

Q2 Who are "Health Care Professionals"? Does the term include non-clinical people who make Medical Technology purchasing decisions? Does it include decision-makers within GPOs?

The phrase "Health Care Professionals" is intended to be a broad one. It includes individuals or entities: 1) which are involved in the provision of health care services and/or items to patients; and 2) which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies in the United States. The phrase Health Care Professional includes both persons providing services (such as licensed physicians) and persons who do not provide services directly but who are involved in the decision to purchase, lease, or recommend a Medical Technology. These individuals include, for example, purchasing agents, physician's practice managers and management within group purchasing organizations ("GPOs").

Q3 Does the Code apply to gifts, meals, refreshments, and other benefits provided by Companies to government employees?

Yes, the Code applies to gifts, meals, refreshments, and other benefits provided by Companies to government employees if the employees are Health Care Professionals. Companies also should be aware that there may be specific legal restrictions on providing gifts and other benefits to government employees, and that these restrictions may, in some cases, be more restrictive than the Code.

Q4 Does the Code cover interactions with Health Care Professionals whose primary place of work is outside the U.S.? Does it cover interactions outside the U.S. with Health Care Professionals who work in the U.S.?

The Code applies to interactions with Health Care Professionals to the extent that they provide

services or Medical Technologies in the United States. This would include interactions with Health Care Professionals who work in the United States, even if the interaction occurs outside the country (such as at a conference or other event). Of course, there are other laws and ethical requirements that may pertain to interactions with Health Care Professionals located both inside and outside the United States.

Q5 Are combination products covered by the Code?

Yes, interactions related to combination products (e.g., those that are both biologics and devices or drugs and devices) are covered by the Code. Interactions related to combination products also may be subject to the ethical codes of other trade associations.

Q6 Does the Code address arrangements between a Company and a Health Care Professional relating to licensing a new product to the Company?

If these arrangements involve providing services to a Company, they are a type of consulting arrangement addressed in Section VI.

Q7 What do the terms "modest" and "occasional" mean?

“Modest” means moderate value, but may differ depending on regional differences. “Occasional” means infrequent. The provision of meals is subject to the limits discussed in Section VIII. A Company should consider establishing limits on the frequency and costs of meals provided to Health Care Professionals to comply with the requirements that the meals must be “modest” and “occasional.”

Q8 May a Company's employee or agent pay for meals or refreshments for a Health Care Professional that a Company could not provide under the Code, if the Company neither pays for the meals or refreshments nor reimburses the employee or agent?

No. The Code should be viewed as applying to a Company's employees and agents even if they pay for benefits themselves. Depending on the circumstances, it may be appropriate for an employee or agent of a Company to engage in certain activities with a Health Care Professional if each pays his or her own way.

Q9 May a Company offer to provide laptop computers with independent value to any purchasing manager whose hospital purchases at least 1,000 units of the Company's medical technology that the Company has just introduced?

No. A Company may not provide any item of value to a Health Care Professional that takes into consideration the value or volume of the business that is or may be generated by the Health Care Professional, unless permitted by law (e.g., appropriate discounts).

Q10 May a Company provide support for a Health Care Professional-sponsored social event, such as an office holiday party?

No, such support would be inappropriate.

SECTION II: CODE OF ETHICS COMPLIANCE

Q11 What form should Companies use to make the certification described in Section II, and on what date are such certifications due?

The revised AdvaMed Code of Ethics will take effect on July 1, 2009. Company certifications should be submitted no later than July 1 of each year, beginning in 2010. AdvaMed will publish the certification form that Companies should use. While it may take a period of time for Companies to adopt the revised Code, create and implement policies, procedures and effective compliance programs to comply with the Code, and educate and train employees whose job responsibilities make the information relevant, Companies should endeavor to accomplish these tasks as diligently as reasonably possible.

Q12 Does the AdvaMed Code of Ethics offer legal advice?

No. The Code is intended to facilitate ethical behavior and is not intended to be, nor should it be, construed as legal advice. All Companies have an independent obligation to ensure that their interactions with Health Care Professionals comply with all applicable laws and regulations.

Q13 Will AdvaMed staff provide advice on how the Code would apply to specific practices?

No. Companies should address questions about specific practices to their own attorneys or advisors.

Q14 Does the Code govern the actions of Companies' agents and distributors?

As stated in Section II, Companies adopting the Code are required to communicate the Code's provisions to their employees, agents, dealers and distributors with the expectation that they will adhere to them. It is important that these entities are informed that AdvaMed has revised its Code of Ethics and that they are aware of the ethical standards reflected in it.

Q15 What does "appropriately tailored" mean with respect to implementation of the seven elements of an effective compliance program?

"Appropriately tailored" means that each Company's implementation of the seven elements of an effective compliance program should take into account the Company's size, resources, particular lines of business, and work-force. AdvaMed recognizes that, given the wide diversity within the medical technology industry, there is no single best compliance program. AdvaMed strongly encourages Companies to develop and implement compliance elements that address the specific types of risks that apply to their operations.

SECTION III: COMPANY-CONDUCTED PRODUCT TRAINING AND EDUCATION

Q16 Why may it be appropriate under the Code for Companies to pay for travel to attend training and education sessions?

In order to efficiently deliver training and/or education at appropriate facilities, the Code contemplates that a Company may bring Health Care Professionals together at a central location, which may make out-of-town travel necessary. Note that this section deals only with meetings focused on training and education on Medical Technologies, and only for persons who could legitimately benefit from the training and education. (Meetings focused on sales, promotional, and other business meetings are discussed in Section V.)

Q17 May a Company pay for travel to a Company-sponsored general educational program (not related to a Medical Technology)?

It may be appropriate for a Company to conduct a general educational session, but it is not the type of program for which Company-supported travel would be appropriate under the Code. In contrast, paying for a Health Care Professional's travel may be appropriate when the Company is conducting training and education on the safe and effective use of its Medical Technologies.

SECTION IV: SUPPORTING THIRD-PARTY EDUCATIONAL CONFERENCES

Q18 May a Company designate attendees or faculty who will speak at a third-party educational conference?

No. The Code contemplates that an independent third party will select faculty and attendees. The Code does not preclude a Company from recommending a knowledgeable faculty member, where the recommendation is permitted by the conference sponsor's guidelines. The ultimate selection should be made by the conference sponsor.

Q19 May a Company provide an educational grant to support the attendance of a Health Care Professional at a third-party educational conference?

The Code contemplates that grants would be made to the conference sponsor or training institution, which will select the attendees. Furthermore, the Code contemplates that the benefited attendees would be medical students, residents, fellows, or other Health Care Professionals in training.

Q20 If a Company provides a grant for a medical student to attend an educational conference, may the funds be used to cover both travel expenses and registration fees?

Yes, provided that the grant is given directly to a training institution or a third party educational conference sponsor.

Q21 May a Company sponsor an off-site sales, promotional, or other business meeting that is ancillary to a third-party educational conference?

Yes, provided that the sales and promotional meeting or other activity has a legitimate business purpose and meets all applicable requirements of the Code. The Company also should comply with applicable conference sponsor guidelines.

SECTION V: SALES, PROMOTIONAL, AND OTHER BUSINESS MEETINGS

Q22 Why does the Code not allow Companies to extend business courtesies to guests/spouses in connection with sales, promotional and other business meetings?

AdvaMed's Code of Ethics is mindful of the desire to avoid even the appearance that business courtesies are being given as improper inducements to promote a Company's Medical Technologies. On the other hand, Companies may, as a matter of common courtesy and civility, provide occasional modest meals or refreshments for Health Care Professionals in connection with these types of meetings that are conducive to the exchange of information. The Code precludes the extension of these courtesies to persons, such as guests/spouses, without a *bona fide* professional interest in the meeting.

Q23 May a Company conduct a sales, promotional, or other business meeting at a resort location and pay for a Health Care Professional's travel to the meeting?

Generally, this would not be appropriate. Companies should be deliberate in selecting the location and venue for such meetings. Like location and venue selection for training and education meetings (discussed in Section III), Companies should select a location and venue that is appropriate for, and conducive to, accomplishing the purpose of the meeting. Selection of a resort location would not likely meet these standards and may give rise to an appearance of impropriety. In addition, the location should be evaluated for consistency with the provisions in Section V, which state that it may be appropriate at sales, promotional, or other business meetings to provide occasional modest meals or refreshments and, with respect to providing travel, that the travel be "necessary." Furthermore, the Code provides for limited special circumstances of "plant tours and demonstrations of non-portable equipment" as specific examples of when travel might be necessary.

Q24 May a Company indirectly provide meals or refreshments when the provision of meals or refreshments does not conform to the Code, for example, by reimbursing a distributor who provides these meals while marketing the Company's Medical Technologies?

No. Companies should always promote adherence to the Code by intermediaries when they are engaged in marketing the Company's Medical Technologies. A Company should never knowingly encourage or condone an intermediary's engaging in conduct that would be prohibited by the Code if a Company engaged in it directly.

SECTION VI: CONSULTING ARRANGEMENTS WITH HEALTH CARE PROFESSIONALS

Q25 Is a clinical investigator considered a “consultant” under Section VI?

If the clinical investigator is providing services to the Company in return for compensation, he or she is a consultant under Section VI.

Q26 Is there a limit to the number of consultants a Company may retain under Section VI?

Companies may retain only as many consultants as are necessary to fulfill the Company's requirements for *bona fide* services; moreover, the requirements of Section VI must be satisfied for each consultant.

Q27 May a consultant be placed under retainer with services provided as requested?

Yes, provided the requirements of Section VI are met.

Q28 What happens if a consultant is engaged but the project is cancelled or modified without using the consultant's services?

The Code contemplates that if the requirements of Section VI were met when the consultant was engaged and then unanticipated circumstances prevented performance, then the question of whether or how much payment is made to a consultant would be a matter determined by the underlying consulting agreement. However, any such payment should be reasonable under the circumstances.

Q29 What factors should a Company consider when evaluating the venues and circumstances for meetings with consultants?

A Company should assess (a) whether there is a *bona fide* business justification for holding the meeting; (b) whether the location and venue are suitable for and conducive to the exchange of information; (c) whether the value of any Company-sponsored lodging is reasonable; (d) whether any ancillary meals and refreshments are modest in value and are subordinate in time and focus to the business part of the meeting; and (e) whether the overall meeting has a genuine business purpose and tenor and does not constitute an unlawful inducement.

Q30 Do the restrictions of the AdvaMed Code apply to Company interactions with consultants in the same way as they do to interactions with other Health Care Professionals?

Yes. All interactions with Health Care Professionals must meet the requirements of the Code. These include the requirements of Section VI as well as other applicable sections of the Code.

Q31 When is a Health Care Professional considered a "consultant"? What types of arrangements with consultants are covered under Section VI?

Any relationship between a Health Care Professional and a Company where services provided to the Company by the Health Care Professional are exchanged for remuneration constitutes a consulting arrangement and should comply with Section VI. Examples of consulting arrangements include agreements to provide education and training, speaking engagements, proctoring and preceptorships, reference center or center of excellence arrangements, participation on advisory boards or focus groups, medical technology development and research services arrangements (such as post-market research agreements, research and development agreements and clinical studies), and arrangements for the development and/or transfer of intellectual property. Research and educational grants are not considered consulting arrangements. They are addressed in Section XI.

Q32 Can the selection of a consultant include his or her experience, usage or familiarity with a specific Company Medical Technology?

Section VI provides that a consultant should be selected on the basis of his or her qualifications and expertise to meet a defined need. It is possible that these qualifications could include experience with, usage of, or familiarity with a specific Medical Technology. However, neither selection of, nor compensation paid to, consultants should be to reward past usage or constitute an unlawful inducement.

Q33 How are Clinical Study Agreements treated under the Code?

Arrangements that involve the provision of clinical research services by a Health Care Professional in return for compensation are a type of consulting arrangement and are subject to the same principles as other consulting arrangements under the Code. They should be governed by a written services agreement, and compensation should be based on fair market value for the services provided. The clinical program for which the services are being provided should fulfill a legitimate research purpose.

A Clinical Study Agreement typically is entered into between a Company and a Health Care Professional that is a facility, institution, or practice group, and compensation for the clinical research services is paid to that entity. An individual Health Care Professional may act as a study investigator but also provide related services in his or her individual capacity that is outside the scope of the services covered in the clinical study agreement (*e.g.*, protocol development). In that case, it may be appropriate to enter into a separate consulting arrangement with that Health Care Professional.

Q34 How can a Company establish "fair market value"?

There are different valuation methods that may be used to establish fair market value. In all instances, a Company should use objective, verifiable criteria. The method or methods used by a Company should be documented.

Q35 What is considered a "legitimate need" to engage a Health Care Professional as a consultant?

A legitimate need arises when a Company requires the services of a Health Care Professional in order to achieve a proper business objective. There are many proper business objectives. However, engaging a Health Care Professional for the purpose of generating business directly from such Health Care Professional (or a health care provider that is affiliated with the Health Care Professional) is not a proper business objective. Thus, there is a legitimate need to engage a Health Care Professional only if the arrangement would have been entered into absent an opportunity to generate business directly from the Health Care Professional. Further, the level of consulting services to be obtained from a Health Care Professional should not exceed the amount that is reasonably necessary to achieve a Company's proper business objective.

SECTION VII: PROHIBITION ON ENTERTAINMENT AND RECREATION

Q36 May a Company's employee or agent pay for entertainment or recreation for a Health Care Professional that a Company could not provide under the Code, if the Company neither pays for the entertainment or recreation nor reimburses the employee or agent?

No. The Code should be viewed as applying to a Company's employees and agents even if they pay. Depending on the circumstances, it may be appropriate for an employee or agent of a Company to engage in certain activities with a Health Care Professional if each pays his or her own way.

SECTION VIII: MODEST MEALS ASSOCIATED WITH HEALTH CARE PROFESSIONAL BUSINESS INTERACTIONS

Q37 Is a general discussion to build good business relationships a "business presentation" such that it is appropriate to provide a business meal?

No. A business presentation may include substantial discussions related to medical technology development and improvement of a medical technology, pricing, or contract negotiations. The business discussion should account for most of the time spent during the meal. Development of general goodwill and business relationships should not be the primary purpose of a business meal, and a business meal should not be used for entertainment or recreational purposes.

SECTION IX: EDUCATIONAL ITEMS; PROHIBITION ON GIFTS

Q38 May a Company provide a gift such as flowers, gift baskets, meals, snacks, wine, or other refreshments to a Health Care Professional or a Health Care Professional's office or staff?

No. These types of gifts and refreshments are not considered educational items or for the benefit of patients.

Q39 May a Company give gifts to staff of a Health Care Professional who are not themselves Health Care Professionals?

Gifts given to the staff of a Health Care Professional should be treated as though they are given to the Health Care Professional and are subject to all applicable provisions of the Code.

Q40 May a Company or its representative provide a gift to recognize a life event for a Health Care Professional, such as a wedding, birth, anniversary, or death of a family member?

No. A Company, or representative acting on the Company's behalf, may only provide items to Health Care Professionals that are intended for the benefit of patients or serve a genuine educational function for the Health Care Professional. Gifts such as flowers, fruit baskets, etc. do not meet this requirement even if provided to recognize a significant life event.

Q41 May a Company raffle an item during a trade show, such as two round-trip airline tickets, that it could not otherwise give as a gift?

No. A Company may not raffle or give away at a trade show an item that it could not otherwise give a Health Care Professional under Section IX.

Q42 What types of items are considered to be for the benefit of patients?

Items intended for the benefit of patients could include starter kits, and educational brochures, for example. However, "scrubs" and office supplies would not be considered an item for the benefit of patients. With respect to starter kits, a Company should adopt appropriate safeguards regarding the provision of such kits to ensure they are not offered as an unlawful inducement.

SECTION X: PROVISION OF COVERAGE, REIMBURSEMENT, AND HEALTH ECONOMICS INFORMATION

Q43 Is it appropriate to demonstrate that a Medical Technology can be used in an economically efficient manner?

It may be appropriate for Companies to provide accurate information relating to the costs, savings and revenues associated with the use of its Medical Technologies. Without this information, it may be difficult for a Health Care Professional to properly evaluate their economic feasibility or desirability.

SECTION XI: RESEARCH AND EDUCATIONAL GRANTS AND CHARITABLE DONATIONS

Q44 What is an example of a grant or donation to "individuals engaged in genuine charitable missions for the support of that mission"?

One example is providing medical technologies to individuals who perform volunteer disaster relief abroad. Supporting disaster relief work may be appropriate under the Code,

notwithstanding that the individuals or group are acting as independent volunteers and not under the umbrella of a not-for-profit, charitable organization.

Q45 May a Company make a charitable contribution to a not-for-profit institution to pay the registration or seminar fees and travel expenses for an affiliated Health Care Professional to attend a third-party educational conference?

In general, Section IV does not permit a Company to pay directly for the registration, seminar fees or travel expenses of a Health Care Professional's attendance at a third-party educational conference. Consequently, the Company should not provide these benefits indirectly as a charitable contribution to a Health Care Professional's not-for-profit institution for the purpose of defraying the costs of particular individuals' attendance. However, it can provide grants to sponsors to: 1) pay the expenses of faculty members selected by the conference sponsor; 2) support the participation of Health Care Professionals in training; or 3) reduce the costs of participation by all participants.

Q46 May a Company make a charitable contribution to a not-for-profit hospital for construction of a new wing?

Companies have historically supported the delivery of health care services through charitable contributions. As with any other contribution, this type of contribution may be appropriate if: (a) the recipient of the contribution is a charitable organization; (b) the purpose of the donation is charitable in nature; and (c) it is not an unlawful inducement. Many factors would be involved in considering whether such a contribution is appropriate, including ensuring that the amount of the donation is not dependent upon the volume of business or anticipated business conducted with or referred to the Company.

Q47 May a Company make an educational grant to pay for a clinical fellow?

A Company may make an educational grant to an institution to subsidize a clinical fellow if the fellow is in a genuine fellowship program which has a charitable or academic affiliation. A Company may not use the provision of an educational grant as an unlawful inducement.

Q48 May a Company pay for or provide tickets to a Health Care Professional or spouse or guest to attend charitable events, such as galas and golf outings?

No. A Company may not pay for or provide tickets to Health Care Professionals or their spouses or guests to attend charitable events, such as galas and golf outings.

Q49 May a Company give a Health Care Professional a research grant that is unrestricted and can be used for any purpose?

No. A Company should give research grants only if they are in support of research that has defined goals, objectives, and milestones.

Q50 May a Company make a contribution in support of a Health Care Professional's charitable event (e.g., golf tournament, outing, gala dinner, and the like), where the proceeds earned from the event will be used for charitable purposes?

Yes, so long as the donation is not an unlawful inducement. However, a Company may not pay for an individual Health Care Professional to attend or participate in the charitable event.

Q51 How can a Company determine whether a charitable organization is a *bona fide* charitable organization?

Companies should exercise diligence to ensure the charitable organization is *bona fide*. Relevant factors to consider may include (1) the entity's tax status, (2) the entity's corporate status under state law, and (3) whether the organization has a charitable mission or purpose, among other factors.

SECTION XII: EVALUATION AND DEMONSTRATION PRODUCTS

Q52 May a Company provide a recently approved product without charge to a Health Care Professional for evaluation?

Yes, but the Company should provide the Health Care Professional with documentation about the product to allow the Health Care Professional to appropriately address any obligation to report for reimbursement purposes.

Q53 A Health Care Professional has requested that a Company provide it with a multiple use product to evaluate. How long can the Company provide the product at no charge to the Health Care Professional?

The specific length of time reasonably necessary for a Health Care Professional to assess a multiple use product will depend on the frequency of anticipated use, the duration of required training, the number of Health Care Professionals who will need to evaluate the product, the length of time necessary to evaluate different product features, and similar considerations. A Company should provide a Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation products.

Q54 Is a demonstration or evaluation product that is provided at no charge to a Health Care Professional by a Company a gift?

No. Demonstration and evaluation products are not considered gifts under Section IX.